

TITLE 22. EXAMINING BOARDS
Part 15. Texas State Board of Pharmacy
Chapter 291. Pharmacies
Subchapter F. Non-resident Pharmacy (Class E)

22 TAC §291.104

The Texas State Board of Pharmacy proposes amendments to §291.104 concerning Operational Standards in a Class E (Non-Resident) Pharmacy. The amendment, if adopted, will specify that Class E Pharmacies must comply with the provisions of new §291.25 and/or §291.26 if they compound non-sterile or sterile pharmaceuticals and dispense those products to patients in Texas.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state government as a result of enforcing or administering the rule. There are no anticipated fiscal implications for local government.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be the establishing of standards for the compounding of non-sterile pharmaceuticals by pharmacies. There is no fiscal impact anticipated for small or large businesses or to other entities who are required to comply with this section.

A public hearing to receive comments on the proposed amendment will be held at 9:00 a.m. on Tuesday, November 18, 2003, at the Health Professions Council Board Room, 333 Guadalupe Street, Tower II, Room 2-225, Austin, Texas 78701. Persons planning to present comments to the Board are asked to provide a written copy of their comments prior to the hearing or bring 20 copies to the hearing. Written comments on the amendment may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, 333 Guadalupe Street, Suite 3-600, Austin, Texas, 78701, FAX: 512/305-8082, E-mail: allison.benz@tsbp.state.tx.us. Comments must be received by 5 p.m., November 12, 2003.

The amendment is proposed under sections 551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551-566 and 568-569, Texas Occupations Code). The Board interprets section 551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets section 554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act. The Board interprets section 554.051(b) as authorizing the agency to make a rule concerning the operation of a licensed pharmacy located in this state applicable to a pharmacy licensed by the board that is located in another state, if the board determines the rule is necessary to protect the health and welfare of the citizens of this state.

The statutes affected by this rule: Chapters 551-566 and 568-569, Texas Occupations Code.

The agency hereby certifies that the proposed amendment has been reviewed by legal counsel and found to be a valid exercise of the agency's authority.

§291.104. Operational Standards

(a) *Licensing requirements.*

(1) - (9) (No Change.)

(10) A Class E (Non-Resident) pharmacy engaged in the compounding of non-sterile pharmaceuticals shall comply with the provisions of §291.25 of this title (relating to Pharmacy Compounding of Non-sterile Pharmaceuticals).

(11) A Class E (Non-Resident) pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.26 of this title (relating to Pharmacy Compounding of Sterile Pharmaceuticals).

(b) - (f) (No Change.)